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Attorney Docket No. P21587

In re application of : Naoyuki NISHIKAWA et al.

Serial No. : 09/926,355

Filed : October 19, 2001

For : TRICYCLIC COMPOUNDS

Mail Stop Non-Fee  
Group Art Unit : 1626

Examiner : A. SMALL

**RECEIVED****MAY 15 2003**

Mail Stop Non-Fee  
COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**TECH CENTER 1600/2900**

Sir:

Transmitted herewith is an Election with Traverse in the above-captioned application.

☐ Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a previously filed statement.

☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.

☐ An Information Disclosure Statement, PTO Form 1449, and references cited.

☒ No additional fee is required.

The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims: 29	*29	0	x 9=	\$	x 18=	\$0.00
Indep. Claims: 2	**3	0	x 42=	\$	x 84=	\$0.00
Multiple Dependent Claims Presented			+140=	\$	+280=	\$0.00
Extension Fees for Month				\$		\$0.00
Total:				\$	Total:	\$0.00

\*If less than 20, write 20

\*\*If less than 3, write 3

☐ Please charge my Deposit Account No. 19-0089 in the amount of \$\_\_\_\_\_.

☐ N/A A Check in the amount of \$\_\_\_\_\_ to cover the \*filing/extension\* fee is included.

☒ The U.S. Patent and Trademark Office is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.

☒ Any additional filing fees required under 37 C.F.R. 1.16.

☒ Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 CFR 1.136)(a)(3).

Bruce H. Bernstein  
Reg. No. 29,027  
3/1296

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Naoyuki NISHIKAWA et al.

Group Art Unit: 1626

Serial No : 09/926,355

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Filed : October 19, 2001

For : TRICYCLIC COMPOUNDS

**ELECTION WITH TRAVERSE**

Commisioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

This is in response to the requirement for restriction and election of species mailed from the U.S. Patent and Trademark Office on April 14, 2003, which sets a one-month shortened statutory period for response until May 14, 2003. In view of the fact that this Response is being timely filed, no extension of time is believed necessary; however, should the Patent and Trademark Office determine that an extension is necessary, the same is hereby requested and The Commissioner is hereby authorized to charge any additional fee to Deposit Account No. 19-0089.

Reconsideration and withdrawal of the requirement for restriction and election are respectfully requested in view of the remarks which follow:

DISCUSSION OF RESTRICTION AND ELECTION REQUIREMENTS

The Examiner has determined that many distinct inventions are contained in this application, including:

- I Claims 1-5 and 7-21 in part drawn to products of the formula (I) wherein A is formula I(a); L is -NR<sup>5</sup>-C(O)- and X is -NR<sup>5</sup>-C(O)- or NR<sup>5</sup>SO<sub>2</sub>- and one method of use (e.g., treating diabetes).
- II Claims 1-5 and 7-21 in part drawn to products of the formula (I) wherein A is formula I(b); L is -NR<sup>5</sup>-C(O)- and X is -NR<sup>5</sup>-C(O)- or NR<sup>5</sup>SO<sub>2</sub>- and one method of use (e.g., treating diabetes).
- III Claims 1-5 and 7-21 in part drawn to products of the formula (I) wherein A is formula I(c); L is -NR<sup>5</sup>-C(O)- and X is -NR<sup>5</sup>-C(O)- or NR<sup>5</sup>SO<sub>2</sub>- and one method of use (e.g., treating diabetes).
- IV Claims 1-4 and 6-21 in part drawn to products of the formula (I) wherein A is formula I(a); L is -C(O)-NR<sup>5</sup>- and X is -NR<sup>5</sup>-C(O)- or NR<sup>5</sup>SO<sub>2</sub>- and one method of use (e.g., treating diabetes).
- V Claims 22-29 in part drawn to products of the formula (IV) wherein A is a 5 membered hydrocarbon ring; L is -NR<sup>5</sup>-C(O)-, etc.

The Examiner contends that a restriction requirement is appropriate under LACK OF UNITY rules, PCT rules 13.1 and 13.2.

The action states that Applicants are required to elect a single invention from Groups I - V or may choose another embodiment not listed. Alternatively, the action states that Applicants may elect a species which the Examiner will attempt to group.

ELECTION AND PROPOSED GROUP

In order to be responsive to the requirement for restriction, Applicants propose a group for purposes of Examination, with traverse. Specifically, Applicants propose a group wherein

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(with respect to Formula I), A is (Ib) or a 6-membered aromatic ring, L is -NR<sup>3</sup>-CO-, X is -NR<sup>5</sup>-CO, -NR<sup>5</sup>-SO<sub>2</sub>- or a single bond. Subject to approval of the group by the Examiner, Applicants elect this group with traverse. Applicants note that at least claims 1-5 and 7-21 are readable thereon. Additionally, Applicants note that Compound No. 5-20 (page 34), Example 102 is within this group and to the extent a selection of species is required in view of the foregoing proposed group, Applicants elect this species for examination. With regard to the election of species requirement (should one be imposed) it is understood that (a) the requirement will be withdrawn upon the finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found patentably distinct from the elected or allowed claims.

However, for the reasons set forth below, Applicants submit that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

### TRAVERSE

Notwithstanding the election of the proposed group in order to be responsive to the requirement for restriction, Applicants respectfully traverse the requirement.

As noted above, the Examiner contends that the inventions are distinct, each from the other and a restriction requirement is appropriate under LACK OF UNITY rules, PCT rules 13.1 and 13.2, which permit in a single application claims to alternatives of chemical compounds. In contrast to this assertion by the Examiner, Applicant points out that in determining unity of invention the criteria set forth in 37 C.F.R. 1.475, as well as M.P.E.P § 1850, must be considered.

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Specifically, §1.475(a) sets forth the definition of the requirement for unity of invention, and the unity of invention that must be satisfied, where a group of inventions is claimed, in order to have the right to include multiple inventions in a single application. In particular, §1.475(a) states that a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. In this regard, it is stated that:

Where a group of inventions is claimed in an application, the requirement for unity of invention shall be fulfilled only when there is technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art.

M.P.E.P. § 1850(D) provides amplification and implementation of unity of invention with respect to Markush practice, as is the case with the instant claims. This section provides:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or [emphasis added by applicants herein]
- (C)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

In paragraph (C)(2), above, the words “recognized class of chemical compounds” mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

In the instant situation all of the alternatives have a common property or activity (see, e.g., specification, pages 4 and 5)) and share a significant structural feature (i.e., the core of formula (I).

The instant restriction requirement is therefore improper.

In view of the foregoing, it is respectfully requested that the Examiner seriously reconsider the requirement for restriction, and withdraw the same so as to give an examination on the merits on all of the claims pending in this application.

#### CONCLUSION

For the reasons discussed above, it is respectfully submitted that the requirement for restriction is improper because unity of invention is present, and the requirement should be withdrawn.

Withdrawal of the requirement for the restriction with examination of all pending claims is respectfully requested.

Favorable consideration with early allowance of claims 6-18 is most earnestly requested.

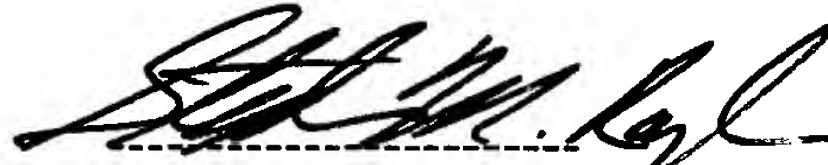
If the Examiner has any questions, or wishes to discuss this matter, the Examiner is

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respectfully requested to call the undersigned at the telephone number indicated below.

The Commissioner is hereby authorized to credit any overpayment or charge any additional fee to Deposit Account No. 19-0089.

Respectfully submitted,  
Naoyuki NISHIKAWA et al.



Bruce H. Bernstein  
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May 14, 2003  
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